NADL
National Association of
Dental Laboratories

Established in 1951

September 28, 2005

Mr. Michael E. Adjodha
Center for Devices and Radiological Health (HFZ-480)
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

Re: Comments of the National Association of Dental Laboratories Regarding the Meeting of the Dental Products Panel on Mouthguards

The National Association of Dental Laboratories (NADL) submits these comments to the Dental Products Panel in advance of its meetings on October 11 and 12, 2005, with regard to its proposal to classify dental mouthguards. The NADL does not object to regulatory classification for mouthguards used to provide protection against bruxism, teeth clenching and grinding. However, the NADL wishes to confirm that neither the Panel nor FDA intend to require dental laboratories that prepare mouthguards pursuant to a dentist's prescription to file a 510(k) for those mouthguards, or to change the regulatory status of dental laboratories to require that they register with FDA when preparing mouthguards. It is our understanding that this is not the Panel or FDA's intention.

The NADL is the national association representing both the dental laboratory industry and the dental technician professions. It represents approximately 1,500 dental laboratories on matters relating to scientific, business, legal and regulatory developments. The NADL is in frequent contact with FDA on matters relating to dental health care, and dental laboratories in particular.

As you know, dental laboratories occupy a somewhat unique place in the healthcare delivery system, and in FDA's regulatory scheme. Dental laboratories typically custom manufacture medical devices, such as full and partial dentures, bridges and crowns, to the specifications or orders of dentists. These products are ordered for specific patients, on a case by case basis. FDA recognizes the unique nature of this relationship, and regulates bridges and crowns, and the labs that prepare them, in a unique way. FDA does not classify individual finished crowns or bridges as medical devices, and does not require dental laboratories to submit 510(k) premarket notifications for them. Rather, the agency classifies the component materials used to fashion the crowns and bridges as medical devices.[1] The manufacturers of those component materials must file 510(k)s, but once those are cleared, no further filing is necessary.

[1] See, *e.g.*, 21 C.F.R. § 872.3060, classifying noble metal alloys "intended for use in the fabrication of cast or porcelain-fused-to-metal crown and bridge restorations."

Similarly, FDA generally exempts dental laboratories from the requirement that manufacturers of medical devices register with FDA and provide a list of their products to the agency. In its regulations, FDA has utilized its discretion under the Federal Food, Drug, and Cosmetic Act (FDCA) 21 U.S.C. § 360, to determine that certain types of facilities do not require registration in order to protect public health. Specifically, the agency exempts from the registration requirement for domestic manufacturers:

> [p]ersons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example a . . . *dental laboratory* . . . whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.[2]

This provision is similar to FDA's general rule that registration is not required for a person who manufactures devices for another party that initiates specifications and commercially distributes the device.

The preparation and distribution of mouthguards is very similar to that for bridges and crowns. Because the laboratories role would remain consistent with that for which they were granted an exemption from registration, the regulatory status of dental laboratories should not change if a regulatory classification is put into place for mouthguards. Dental laboratories receive orders from dentists for mouthguards, setting out specifications for particular patients. The laboratories then prepare the mouthguards from commercially sold component materials that they have purchased from registered manufacturers. The laboratories' activities remain exactly those described in the regulatory exception from registration, *i.e.*, they dispense devices to the ultimate consumer, and their "major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device." Creation of a regulatory classification for mouthguards does not alter the role of the dental laboratories, and should not alter their exemption from registration.

It is also worth noting, as a practical matter, that if FDA were to alter the registration requirement for dental laboratories based on a new regulatory classification for the mouthguards, or require the laboratories to submit 510(k)s for the mouthguards they prepare, it would ultimately reduce access to the products. Most dental laboratories are small operations, with a staff of just a few people. Typically, they cannot spare the personnel or the resources to prepare 510(k) submissions, or to go through the regulatory submissions, monitoring and updating associated with registration and listing. If FDA were to require 510(k) submissions and registration for dental laboratories that prepare mouthguards, most simply would cease providing them, rather than take on the additional regulatory burden. This would create an obstacle to access for consumers, as only the largest laboratories, a handful of the total, would be available to provide

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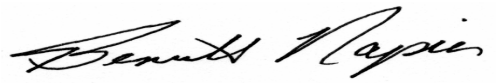
[2] 21 C.F.R. § 807.65(i). (emphasis added). This exemption applies only to the registration requirement for domestic manufacturers. Thus, only domestic dental laboratories are exempt from registration. FDA did not make such a finding for dental labs located outside the United States. Foreign labs remain subject to the registration requirement for foreign manufacturers.

mouthguards. The result would be to undermine FDA's goals of making higher quality mouthguards fitted by dentists more readily available to the public.

Based on our previous communications with FDA, it is the NADL's understanding that neither the Dental Products Panel nor the agency intend to alter the current regulatory status of dental laboratories with regard to registration and filing of 510(k)s for mouthguards. NADL provides these comments to reiterate its position, and hopefully that of the Panel as well.

Thank you for your consideration of our position. If NADL can provide any additional information, please do not hesitate to contact me or Ricki Braswell, CAE at (800) 950-1150.

Sincerely,



Bennett Napier, CAE

Co-Executive Director